

### **REMARKS**

This Submission is responsive to the Office Action mailed May 1, 2008. Claims 34, 36-39 and 41-46 are pending in the application.

In this Submission, claims 34, 36-38, 43, and 45 have been canceled without prejudice. Claims 39 and 46 have been amended as discussed below.

### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH – ENABLEMENT**

At page 2 of the Office Action mailed May 1, 2008, claims 39, 41-44 and 46 were rejected as not enabled. The Examiner alleged that the specification, while enabled for the treatment of infection caused by bacteria and malaria, does not reasonably provide enablement for a method of treating infection caused by other infectious agents.

Applicants traverse this rejection. Claim 39 has been amended to state that the infectious agent is selected from the group consisting of fungi, unicellular parasites, multicellular parasites, and viruses. Claim 43 has been canceled without prejudice. Claim 44 has been amended to depend from claim 39. Claims 41 and 42 depend directly or indirectly from claim 39. Claim 46 has also been amended to state that the infectious agent is selected from the group consisting of fungi, unicellular parasites, multicellular parasites and viruses. Support for the amendments to claims 39 and 46 can be found throughout the specification and in particular at page 12, lines 22-25, and claim 43, now canceled.

Applicants respectfully submit that claim 44 is allowable. Claim 44 is directed to the method of claim 39 wherein the infectious agent has the potential to produce a malarial infection in a human subject. In the remarks to the present rejection, the Examiner indicated that the specification enables methods of treatment wherein the infectious agent produces malaria.

Applicants also respectfully submit that persons skilled in the art can practice the methods of the invention with other types of unicellular and multicellular parasites, viruses, and fungi without undue experimentation. Persons skilled in the art can use *in vitro* screening methods and animal models of specific conditions to determine the activity of the compounds of

Formula I, and their suitability for treatment of a particular condition caused by an infectious agent selected from the group consisting of fungi, unicellular parasites, multicellular parasites, and viruses. As discussed in the specification at page 16, last paragraph to page 17, the activity of the compounds of Formula I is determined using a test system based on measuring the inhibition of growth of the parasites, viruses or fungi *in vitro*, or in animal models. Substances which demonstrate efficacy in the *in vitro* measuring systems can then be further evaluated using appropriate animal models. Thus, the specification enables persons skilled in the art to practice the methods of claims 39, 41, 42 and 46 without undue experimentation.

Withdrawal of this section 112, first paragraph rejection is respectfully requested.

#### **REJECTION UNDER 35 USC 102(b)**

At page 6 of the Office Action, the Examiner rejected claims 34, 36-39 and 41-46 under 35 USC 102(b) as anticipated by U.S. patent 4,206,156 (the '156 patent). The Examiner stated that the '156 patent teaches the claimed organophosphorus compounds, methods of preparing such compounds, and methods of administering the compounds for treatment of microbial infection.

Applicants traverse this rejection. Claims 34, 36-38 and 45 have been canceled without prejudice, and the portion of this rejection relating to these claims is now moot.

Claim 39 has been amended to state that infectious agent is selected from the group consisting of fungi, unicellular parasites, multicellular parasites, and viruses. Claim 43 has been canceled without prejudice. Claim 44 has been amended to depend from claim 39. Claims 41 and 42 depend directly or indirectly from claim 39. Claim 46 has also been amended to state that the infectious agent is selected from the group consisting of fungi, unicellular parasites, multicellular parasites, and viruses.

The '156 patent discloses the use of the organophosphorus compounds disclosed therein for treatment of microbial infection, which, as discussed at column 18, lines 10-26, refers to antibacterial activity for treatment of infectious disease caused by pathogenic bacteria. The '156 patent therefore does not anticipate amended claims 39, 41, 42, 44 and 46, which are directed to

methods of treating infection wherein the infectious agent is selected from the group consisting of fungi, unicellular parasites, multicellular parasites, and viruses. Withdrawal of this section 102(b) rejection is respectfully requested.

### **DOUBLE PATENTING REJECTIONS**

At page 7 of the Office Action, the Examiner maintained the rejection of claims 34, 36-39 and 41-46 on the grounds of non-statutory obviousness-type double patenting over claims 1-16 of U.S. Patent 6,680,308. The Examiner stated that, although the conflicting claims are not identical, they are not patentably distinct from each other because the '308 patent recites the same compounds for a method of treating essentially the same infectious diseases.

Applicant again requests that this rejection be held until such time as notice of patentable subject matter has been received in the present application. Applicant will file an appropriate terminal disclaimer at that time if necessary.

The Examiner also rejected claims 34, 36-39 and 41-46 on the grounds of non-statutory obviousness-type double patenting over claims 1-14 of U.S. Patent 6,534,489 (the '489 patent). The Examiner stated that, although the conflicting claims are not identical, they are not patentably distinct from each other because the '489 patent recites the compounds claimed in the present application and the method of using such compounds in treating infection caused by bacteria, virus, fungi and parasites.

Applicant requests that this rejection be held until such time as notice of patentable subject matter has been received in the present application. Applicants will file an appropriate terminal disclaimer at that time if necessary.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is respectfully requested and an early Notice of Allowance is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this

application by this firm) to our Deposit Account No. 03-2775, under Order No. 14519-00003-US. A duplicate copy of this paper is enclosed.

Dated: June 3, 2009

Respectfully submitted,

Electronic signature: /Liza D. Hohenschutz/  
Liza D. Hohenschutz

Registration No.: 33,712  
CONNOLLY BOVE LODGE & HUTZ LLP  
1007 North Orange Street  
P. O. Box 2207  
Wilmington, Delaware 19899-2207  
(302) 658-9141  
(302) 658-5614 (Fax)  
Attorney for Applicant